

COXPAR™

Parecoxib Sodium

Presentation

COXPAR™ (IV/IM) Injection: Each vial contains Parecoxib Sodium INN equivalent to Parecoxib 40 mg.

Description

COXPAR™ (IV/IM) Injection is available as lyophilised powder. Parecoxib sodium is rapidly converted to valdecoxib. The mechanism of action of valdecoxib is by inhibition of cyclooxygenase-2 (COX-2)-mediated prostaglandin synthesis. At therapeutic plasma concentrations in humans, valdecoxib does not inhibit cyclooxygenase-1 (COX-1). By inhibition of both peripheral and central COX-2, valdecoxib reduces the production of prostaglandins that are important mediators of pain and inflammation. COXPAR™ Injection is not potential for dependence, sedation or respiratory depression seen with opioid analgesic agents.

Indications

COXPAR™ is indicated for the management of post-operative pain.

Dosage And Administration

The usual recommended dose is a single 40 mg dose administered intravenously (IV) or intramuscularly (IM), followed every 6 to 12 hours by 20 mg or 40 mg as required, not to exceed 80 mg/day. The IV bolus injection may be given rapidly and directly into a vein or into an existing IV line. The IM injection should be given slowly and deeply into the muscle.

Elderly

No dosage adjustment is generally necessary. However, for elderly female patients weighing less than 50 kg, the recommended dose of COXPAR™ Injection is 20 mg.

Hepatic Impairment

No dosage adjustment is generally necessary in patients with mild hepatic impairment. Introduce COXPAR™ Injection with caution and at half the usual recommended dose in patients with moderate hepatic impairment. There is no clinical experience in patients with severe hepatic impairment.

Renal Impairment

On the basis of pharmacokinetics, no dosage adjustment is necessary in patients with mild to moderate (creatinine clearance of 30-80 mL/min) or severe (creatinine clearance <30 mL/min) renal impairment. However, caution should be observed in patients with severe renal impairment or patients who may be predisposed to fluid retention.

Children

COXPAR™ Injection has not been studied in patients under 18 years old.

Incompatibilities

This medicinal product must not be mixed with other medicinal products and should be reconstituted only with sodium chloride solution (0.9% w/v).

Instructions for Use

Reconstitute COXPAR™ Injection with 2 mL (40 mg vials) sodium chloride solution (0.9% w/v) using aseptic technique. After reconstitution, COXPAR™ Injection should be inspected visually for particulate matter and discoloration prior to administration. The solution should not be used if discolored or cloudy or if particulate matter is observed. To reduce microbiological hazard, use as soon as practicable after reconstitution. The reconstituted product should not be stored in a refrigerator or freezer.

Adverse Effects

The most common adverse reactions, reported in patients who received parecoxib are nausea, mouth dry, flatulence, oesophagitis, gastroesophageal reflux, hypoactive bowel sounds, gastroduodenal ulceration, post-operative anaemia, abdominal pain, constipation, dyspepsia, vomiting, oedema peripheral, alveolar osteitis (dry socket), hypokalaemia, dizziness, hypoesthesia, oliguria, respiratory insufficiency, sweating increased, pruritus etc.

Precautions

Parecoxib should be used with caution in patients with hypertension, hyperlipidaemia, diabetes mellitus, sulfonamide allergy, GI Ulceration, Bleeding, hepatic dysfunction, severe hypotension and pre-existing asthma. The use of an ACE inhibiting medicine (ACE-inhibitor or angiotensin receptor antagonist), and an anti-inflammatory drug (NSAID or COX-2 inhibitor) and a thiazide diuretic at the same time, increases the risk of renal impairment.

Contraindications

COXPAR™ Injection is contraindicated in patients undergoing CABG or other major vascular surgery, patients with established ischaemic heart disease, peripheral arterial disease, patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin, NSAIDs or other COX-2 specific inhibitors and also who have demonstrated allergic-type reactions to sulfonamides.

Use in Pregnancy & Lactation

Pregnancy Category C. The use of COXPAR™ injection during the first trimester and third trimesters should be avoided.

Parecoxib are reported to be transferred into the breast milk of lactating women. Because of the potential for adverse effects in nursing infants from COXPAR™ injection, breast feeding should be discontinued during treatment.

Drug Interactions

Parecoxib have interactions with the following class of drugs:

Aspirin, Methotrexate, ACE-inhibitors, Injectable Anaesthetics, Inhalation Anaesthetics, Glibenclamide, Anticonvulsants, Ketoconazole, Fluconazole, Dextromethorphan, Lithium and Anticoagulants.

Overdosage

There are no specific antidotes. Patients should be managed by symptomatic and supportive care following an overdose.

Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Packs

COXPAR™ (IV/IM) Injection: Each box contains one vial of Parecoxib sodium, one ampoule of 2ml 0.9% NaCl and one sterile disposable syringe (3ml).



Manufactured by
Incepta Pharmaceuticals Ltd
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